

Meeting Notes
Pigment Violet 29 Test Studies Update with BASF Corporation
Phone Conference
July 5th, 2017

Attendance:

Hannah Braun (EPA-CCD)
Lorraine Passe (EPA-CCD)
Doug Parsons (EPA-CCD)
Alie Muneer (EPA-RAD)
Jafrul Hasan (EPA-RAD)
Steve Camenisch (BASF Colors & Effects USA LLC)

Notes:

- EPA informed Sun Chemical about the effort to collect the full FDA petition about Pigment Violet 29's use as a food additive in polymers created by BASF Corporation.
 - EPA originally only had an excerpt of the petition
 - EPA contacted the FDA to see if there was more, especially if they had full study reports
 - FDA responded by sending the full petition which included only two full study reports for an AMES test and water solubility test
- EPA seeks full study reports for studies found in the ECHA database from the REACH registration dossier
 - Two sensitive areas for BASF are:
 - reclaiming costs (such as what OPP does)
 - There is no issue with releasing information to people who would pay for the studies; however, the owners of the studies are concerned that if they submit the studies in full now, then EPA will make the studies publically available and anyone would be able to use these studies for financial gain without compensation to the original creators of the data.
 - Since BASF is a small importer, if they are in the position which they lose too much money, they could pull out of the market
 - BASF Corporation (subsidiary of BASF SE) toxicologists do not have access studies being requested
 - Mr. Camenisch will have to reach out to his colleagues in Europe to identify who owns the studies being requested by the EPA
- Before any studies are given to the EPA, an agreement must be in place between the EPA and owners of the studies in order to protect this intellectual property.
 - Options BASF suggested:
 - Give EPA full study reports then EPA returns them after EPA no longer needs to review them
 - ECHA robust summaries to be modified to meet the EPA's need for transparency
 - EPA posed the question of what would the like to keep confidential?
 - BASF would have to discuss with European colleagues

- If full studies are given to the EPA, a watermark will be on the full study reports
 - BASF would like a verbal agreement between EPA and European companies/study owners for “what” will be released to the public
- BASF along with Sun Chemical and CPMA have exposure information
 - RAD will set-up weekly calls with these entities to discuss PV29 exposures in order to refine the problem formulation
 - CPMA are capable of gathering information from downstream users

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